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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,357	11/14/2001	David F. Carmichael	04185.0005-09000	6940

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FINNEMAN, HENDERSON, FARABOW, GARRETT &
DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20006

[REDACTED]

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/987,357	CARMICHAEL ET AL.
	Examiner	Art Unit
	Gerald G Leffers Jr.	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 December 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 25-42 is/are pending in the application.
- 4a) Of the above claim(s) 27-42 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 25 and 26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Specification

Receipt is acknowledged of a preliminary amendment filed 11/14/01 as Paper No. 7 in which several changes were requested for the specification. It is noted that these changes were indicated for an originally filed copy of the specification filed in the parent applications. Applicants have filed a substitute specification on 1/25/02 (Paper No. 4) which differs in page/line numbering from the originally filed specification. As a consequence of this difference, the changes requested in Paper No. 7 have not been entered into the substitute specification. In order to insure that the desired and necessary changes (e.g. SEQ ID NOS, Table No. 1, etc.) are in the published patent, applicants must resubmit the changes requested in Paper No. 7 and specify that the changes are made according to the appropriate page number and line of the substitute specification (e.g. "at page 7, line 11 of the substitute specification").

In Paper No. 7 applicants cancelled the pending claims (claims 1-24) and submitted new claims (claims 25-42). Claims 25-42 are pending in the instant application.

Election/Restrictions

Applicant's election without traverse of Group I (claims 25-26) in Paper No. 10, filed 12/09/02, is acknowledged. Claims 27-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 25-26 are under consideration.

Information Disclosure Statement

The PTO Form 1449 corresponding to the IDS filed on 2/14/02 as Paper No. 5 has been fully considered and has been mailed with the instant office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 26 is directed to a purified collagenase inhibitor which comprises SEQ ID NO: 1 wherein SEQ ID NO: 1 comprises specific amino acid residues at particular positions within the sequence, and optionally a methionine at position -1 of SEQ ID NO: 1. It is noted that each of the recited residues is identical to that found in SEQ ID NO: 1 of the sequence listing, except for the glycine residue (Gly) at position 28. In the sequence listing, position 28 has a glutamic acid residue (Glu). Applicants have indicated that the support for presentation of claim 26 is derived from claim 84 of parent application 08/474,553, of which the instant application is a continuation. Claim 84 of the '553 application recites that the residue at position 28 is a glutamic acid. Alternatively, it is further noted that there is a Gly residue at position 25 of SEQ

ID NO: 1. In any case, there is no literal support in the originally filed application for a Gly residue at position 28 of SEQ ID NO: 1. Therefore, claim 26 comprises impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is vague and indefinite in that it recites that the purified collagenase inhibitor of claim 25, upon which claim 26 depends, “comprises” SEQ ID NO: 1. The open claim language “comprises” follows relatively closed claim language of claim 25 which recites the limitation that the purified collagenase protein “consists essentially of”. This contradiction implies that the protein of claim 26 may possess additional elements that change the character of the protein of claim 25 and makes unclear what proteins are encompassed by the rejected claim. It would be remedial to amend claim 26 to recite transitional language that is consistent with claim 25 (i.e. “consisting essentially of”).

Claim 26 is further indefinite in that it recites the limitation that SEQ ID NO: 1 “further comprises” specific residues at particular positions of SEQ ID NO: 1. It is unclear how SEQ ID NO: 1 can further comprise specific changes (e.g. Gly at position 28) and still remain SEQ ID NO: 1. In addition, it is unclear how SEQ ID NO: 1 can “further” comprise specific amino acid

residues at particular positions of SEQ ID NO: 1 when those specific residues are already present in SEQ ID NO: 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Stricklin et al (The Journal of Biological Chemistry, Vol. 258, No. 20, pages 12252-12258, 1983; see the entire document) as evidenced by Carmichael et al (PNAS USA, Vol. 83, pages 2407-2411, 1986; see the entire reference).

Stricklin et al is a prior art publication by two of the inventors of the instant application. Stricklin et al teach the purification and characterization of a human skin fibroblast collagenase inhibitor from cultured human skin fibroblasts (e.g. Abstract, Figures 1-4 and Tables I-III). In particular, NH₂-terminal sequencing indicates that the protein purified by Stricklin et al comprises the first 25 amino acids of SEQ ID NO: 1 (e.g. Table III).

The instant specification teaches that the cDNA sequences encoding SEQ ID NO: 1 were obtained from cultured human fibroblast cells (e.g. the Examples). During cloning of the cDNAs encoding the collagenase inhibitor protein of the instant invention, recombinant-phage-containing sequences were selected by their preferential hybridization to synthetic oligonucleotides encoding portions of the primary structure of the desired metalloproteinase

inhibitor, referred to as FIBAC. These portions of the protein sequence correspond in part to those set forth in the Stricklin et al reference (pages 37-38 of the instant specification, bridging paragraph). The specification further teaches that the insert of pUC9-F5/237P10 encodes a collagenase inhibitor biologically equivalent to that isolatable from human skin fibroblasts (i.e. SEQ ID NO: 1; see, e.g., paragraphs 099-0101, pages 40-47). One of skill in the art would necessarily expect, based upon the teachings of Stricklin et al and the instant specification, that the purified protein of Stricklin et al, inherently meets the limitations of claim 25(a) and claim 25(b) (i.e. “consisting essentially of” SEQ ID NO: 1 or SEQ ID NO: 2). That this is true is evidenced by the teachings of Carmichael et al, which is post-filing art detailing the work taught in the instant application. Carmichael et al consistently refer to the collagenase inhibitor of their teachings as the same protein as taught in the Stricklin et al reference (e.g. page 2409, column 1, 1st full paragraph).

Because the Office does not have the facilities for examining and comparing the applicant’s product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
February 24, 2003